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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/699,716	08/27/96	HEATH	D 003/029/SAP

18M1/0711

EXAMINER

CAPUTA, A

ART UNIT

PAPER NUMBER

1817

DATE MAILED: 07/11/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. <b>08/699,716</b>	Applicant(s) <b>Heath et al.</b>
Examiner <b>Anthony C. Caputa</b>	Group Art Unit <b>1817</b>

Responsive to communication(s) filed on \_\_\_\_\_

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire \_\_\_\_ -- \_\_\_\_ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 1-28 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-28 are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1-17, drawn to the DNA, classified in class 435, subclass 69.3.
  - II. Claims 18, 19, 21-24, and 26 drawn to protein and vaccine, classified in class 424, subclass 234.1.
  - III. Claim 20, drawn to antibody, classified in class 424, subclass 387.9.
  - IV. Claims 25 and 27, drawn to a method detection using antibody, classified in class 435, subclass 7.1.
  - V. Claim 28, drawn to drawn to a method of detection using antigen, classified in class 435, subclass 7.1.
2. The inventions are distinct, each from the other because of the following reasons:  
Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein can be used for vaccination.
3. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used for treatment.

Groups II and V drawn to a protein and Groups III and IV drawn to antibodies are distinct since they are products with different structure and biological properties. The claimed antibody is made up of  $F_{ab}$  and  $F_c$  fragments whereas the protein is not. Furthermore, the amino acid composition of the protein is distinct from amino acid composition of the antibody.

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Additionally, the Groups are distinct since methods known in the art used to make the protein of does not require the antibody. For instance, the protein can be made by Merrifield chemical synthesis or DNA.

Groups II -IV drawn to protein or antibodies and Group I drawn to DNA are distinct since they are products with different structure and biological properties. The claimed protein is made of amino acids whereas the claimed DNA are made of nucleotides. Furthermore, methods known in the art used to make the protein require different reagents and parameters from the methods of making DNA encoding the protein and the method of making the protein does not require the DNA. For instance, the protein can be made by Merrifield chemical synthesis or affinity chromatography which does not require the DNA.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. A telephone call was made to John Moran to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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7. Any inquiry concerning this communication should be directed to Dr. Anthony C. Caputa, whose telephone number is 703-308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is 703-308-0196.

Papers related to this application may be submitted to Group 1817 by facsimile transmission. Papers should be faxed to Group 1817 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703)-308-4242.

Anthony C. Caputa, Ph.D.

July 6, 1997



ANTHONY C. CAPUTA  
PRIMARY EXAMINER  
GROUP 1800